DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 15, 2015

Ad Rem Technology SARL
c/o Norman F. Estrin, PhD
Estrin Consulting Group, LLC
9109 Copenhaver Drive
Potomac, MD 20854

Re: K141919
Trade/Device Name: Veinoplus® Sport Neuromuscular Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, GXY
Dated: May 18, 2015
Received: May 19, 2015

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141919

Device Name
VEINOPLUS® SPORT Neuromuscular Stimulator

Indications for Use *(Describe)*
The VEINOPLUS® SPORT is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ad Rem TECHNOLOGY
ISO 13485:2003 and ISO 9001:2008
162, rue du Faubourg Saint-Honoré
75008 Paris - France
Tél : +33 (0)1 42 60 00 22
Fax: +33 (0)1 42 60 00 63
info@adremtechnology.com
www.adremtechnology.fr

510(k) SUMMARY (Clean)
Ad Rem Technology Veinoplus® Sport Neuromuscular Stimulator

Sponsor identification	Ad Rem Technology SARL 162 Rue du Faubourg Saint- Honoré 75008 Paris, France Ms. Noémie Dumérain, Quality and Regulatory Affairs Manager, nd@veinoplus.com Tel: + 33 (0)1.42.60.00.22; Fax: + 33 (0)1.42.60.00.63
Establishment registration number:	3005671018
Date of preparation	June 13, 2014
Contact person	Norman F. Estrin, Ph.D. Managing Partner Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Email: estrin@yourFDAconsultant.com
Authorized Agent in the United States	Norman F. Estrin, Ph.D. Managing Partner Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Email: estrin@yourFDAconsultant.com
Proprietary Name	Veinoplus® Sport Neuromuscular Stimulator
Trade name	VEINOPLUS® SPORT
Device Classification Name, Product Code, Reviewing Panel, Regulatory Class, (Regulation)	Device, Stimulator, Muscle, Powered, For Muscle Conditioning NGX Physical Medicine, Class II (21 CFR 890.5850) Electrode, cutaneous GXY Neurology, Class II (21 CFR 882.1320)
Indications for use:	The VEINOPLUS® SPORT is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

Device Description	**Design and features:** The VEINOPLUS® SPORT, like a number of legally marketed predicate devices is a traditional battery powered muscle stimulator. It is portable, hand-held device, equipped with one single channel intended to stimulate the calf muscles or other muscles of the body (for example thighs, arms, buttock, back, shoulder or abdomen). The VEINOPLUS® SPORT device has only one operating mode, called program, stored in the internal memory. The output stimulus is low-voltage, low frequency with rectangular voltage waveform. The device is housed in a plastic enclosure, and it is powered by an alkaline 9V primary battery. The accessories include the output cables, battery, user manual and electrode pads. No provisions are made for AC adapters, so the device cannot be connected to line under any circumstances. The VEINOPLUS® SPORT device is supplied with all accessories (as listed below) necessary for a safe and effective session of stimulation. Main unit, cable, the pair of electrodes, battery, lanyard and user manual are packaged in carrying case then packaged in a carton box with printed messages. Refer to the picture in Section 12 Device Description. List of accessories: - 1pair of electrodes VEINOPLUS® Pack. Self-adhesive. Oval shape. Size 8x13 cm. Low resistance. This includes a Hydrogel for the electrodes (Refer to Sections 19 and 23F). - 1 conductor cable for connecting the electrodes. Approximate length (w/o plug) 135 cm. - 1 instruction manual - 1 9V alkaline battery - 1 lanyard - 1 carrying case: L22.5*W4.5*H17cm.
Predicate Devices	Veinoplus® (K072252) Compex® Sport Plus (K083140)

Comparison of the indications for use with the predicate devices:

The proposed device, VEINOPLUS® SPORT, is substantially equivalent to both of its legally marketed Class II predicate devices:

1. The mode 1 (powered muscle stimulator, IPF) of the Veinoplus® with 510k K072252 (except for the indications for use).
2. The mode (program) “active recovery” of the Compex® Sport Plus with 510k K083140.

Summary of technological characteristics of VEINOPLUS® SPORT with its two predicates Veinoplus® and Compex Sport Plus:

Device name:	**VEINOPLUS® SPORT**	**Veinoplus® (mode 1 of stimulation)**	**Compex® Sport Plus (Program Active Recovery)**
510k Number	K141919	K072252	K083140
Intended use:	Muscle electrical stimulation	Muscle electrical stimulation	Muscle electrical stimulation
Indications for use:	The VEINOPLUS® SPORT is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.	Increasing local blood circulation (common claim with predicates). Relaxation of muscle spasm/ Prevention or retardation of muscle disuse atrophy/ Muscle reeducation/ Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis/Maintaining or increasing range of motion.	Stimulate healthy muscles in order to improve or facilitate muscle performance.
Mode of Action:	The VEINOPLUS® SPORT contracts the muscles by electrical stimulation.	The Veinoplus stimulates the muscles, resulting in rhythmic muscles contraction, which then increases the blood flow.	The Active Recovery program produces muscle twitches at a very low frequency. Those twitches act like a massage and induce an increase of the blood flow and a faster reduction of the lactic acid blood level. It facilitates recovery of the stimulated muscles after active muscle training or competition.
Purpose:	Non-Medical	Medical	Non-Medical
Target Population:	Healthy user	Medical patient	Healthy user
Parts to be stimulated:	Calf muscles and other body parts (arms, buttocks, back (neck/shoulders).	Calf muscles	Legs/feet, arms/hands, buttock, back, shoulder or abdomen)
Where used:	Home, hospital, gym, etc.	Home, hospital, gym, etc.	Data unknown

Device name:	**VEINOPLUS® SPORT**	**Veinoplus® (mode 1 of stimulation)**	**Compex® Sport Plus (Program Active Recovery)**
OTC/Rx Only information :	OTC use	Prescription use	OTC use
Energy delivered:	Electrical	Electrical	Electrical
Technical information:			
Power Source:	One Internal 9 V alkaline battery. Types: 522, 6LR61, MN1604 Shape: rectangular Size: 48x25x16 mm; Volume: 20 cm^3	One Internal 9 V alkaline battery Types: 522, 6LR61, MN1604 Shape: rectangular Size: 48x25x16 mm; Volume: 20 cm^3	One NIMH rechargeable battery (4.8V ≥1200 mA/h) (4 cells pack of 1.2V) Type: 4H-AA1500 Shape: cylindrical Size: 1 cell = 14 mm x 47mm , diameter 14 mm; Volume: 7.3 cm^3
Number of output modes	1 mode/program	2 modes/programs : Mode 1 : EMS Mode 2 : TENS	9 modes/programs : Potentiation Endurance Strength Resistance Active recovery Recovery plus Explosive strength Pre warm-up Massage
Timer range	30 minutes	Mode 1: 20 minutes Mode 2: 20 minutes	Potentiation : 3’ 27’’ Endurance: 50’ 23’’+ 5’03’’ of optional warm up Strength: 22’07’’23’’+ 5’03’’ of optional warm up Resistance: 27’33’’23’’+ 5’03’’ of optional warm up Active recovery: 26’40’’23’’+ 5’03’’ of optional warm up Recovery plus: 24’20’’ Explosive strength: 25’18’’ Pre warm up: 25’03’’ Massage: 20’03’’
Number of output channels:	1	1	4
Automatic overload trip	NO	NO	NO
Automatic no load trip	NO	NO	YES
Accessories:	Electrodes, cable, battery	Electrodes, cable, battery	Electrodes, cable, Battery

Device name:	**VEINOPLUS® SPORT**	**Veinoplus® (mode 1 of stimulation)**	**Compex® Sport Plus (Program Active Recovery)**
		(same model and manufacture as Veinoplus Sport)	charger.

Stimulation signal parameters:			
Waveform	Monophasic rectangular asymmetrical	Monophasic rectangular asymmetrical	Biphasic rectangular symmetrical
Max Output Voltage	50 V@ 500 Ohm	50 V@ 500 Ohm	60 V@ 500 Ohm (each phase)
Max Output Current	100 mA@ 500 Ohm	100 mA@ 500 Ohm	120 mA @ 500 Ohm (each phase)
Max Phase Charge (µC)	24µC @500Ω	24µC @500Ω	48µC (each phase) @500Ω
Maximum current density (mA/cm2, r.m.s.)	<14 µA (rms) /cm2 @500Ω	<13 µA (rms)/cm2 @500Ω	Not available
Maximum Average power density (W/cm2, r.m.s.) (using smallest electrode conductive surface area)	<500 µW (r.m.s.) /cm2 (microwatt) @500 Ω Only one size of electrodes is permitted and supplied by the manufacturer.	<10 µW/cm2 (microwatt) @500 Ω Only one size of electrodes is permitted and supplied by the manufacturer.	<12 mW/cm2 (microwatt) @500 Ω
Pulse duration	from 25 to 240 µs	from 25 to 240 µs	400 µs (each phase)
Session duration:	30 mn	20 mn	29 mn including warm-up
Automatic shut-off	Yes at 30 mn	Yes at 20 mn	Yes, at the end of the session
User override Control	Yes	Yes	Yes
Software	Stimulation pre-set program encoded in a microchip	Stimulation pre-set program encoded in a microchip	Stimulation pre-set program encoded in a microchip
Controls	3 controls	3 controls	Similar, 6 controls
Display/interface	LCD Screen and data display	LCD Screen and data display	LCD screen and similar data.
Electrode size/shape	8x13 cm OVAL	8x13 cm OVAL	5x5 cm square and 5x10 cm rectangular

Compliance with safety and performance Standards:			
Biocompatibility	Electrodes material in contact with skin user are compliant with ISO 10993-5 and ISO 109993-10 standards requirements	Electrodes material in contact with skin user are compliant with ISO 10993-5 and ISO 109993-10 standards requirements	Data unknown
Electrical safety	Comply with IEC 60601-1, IEC 60601-1-2 (EMC), IEC 60601-2-10	Comply with IEC 60601-1, IEC 60601-1-2 (EMC), IEC 60601-2-10	Comply with IEC 60601-1, IEC 60601-1-2 (EMC), IEC 60601-2-10

Substantial Equivalence summary:

VEINOPLUS® SPORT is substantially equivalent to Veinoplus® in the perspective of technological characteristics and general intended uses. Both devices are intended for electrical stimulation of muscles. VEINOPLUS® SPORT was developed based on Veinoplus® device and both devices are technically very close. The indications for use of VEINOPLUS®, which is intended to be sold under prescription and for medical purpose, are not used for demonstration of substantial equivalence of VEINOPLUS® SPORT.

VEINOPLUS® SPORT is substantial equivalent to Compex® Sport Plus in term of intended use, indications for use and technological characteristics. The technical differences between VEINOPLUS® SPORT and Compex® Sport Plus (power supply, waveform shape ...) do not raise additional issues of safety

Summary of Non-clinical performance testing:

Compliance to applicable voluntary standards includes IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 and ISO 14971.
The gel of electrodes was tested according ISO 10993-5 and ISO 10993-10 Biocompatibility standards.
In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA guidance for the content of premarket submissions for software contained in Medical Devices.
A usability study support as well that the user can operate the device in a safe and effective manner with labeling supplied with the device.

Conclusion:

The safety and performance of the device is supported by testing with safety and performance standards IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10 standards.
The differences between VEINOPLUS® SPORT® and the predicate devices do not raise new issues of safety and effectiveness.